

Remarks

Claims 1-30 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 4-8, 10, 16, 17, 18, 23-26, and 29 and cancelled claims 3 and 28. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the subject application including, for example, at pages 3 and 4 of the application. Accordingly, claims 1, 2, 4-27, 29, and 30 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the objection set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Claims 1-28 and 30 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants wish to thank Examiner Turk for his careful review of the claims. Claim 1 has been amended to provide sufficient antecedent basis for “the patient.” Further, claims 4, 5, 7, and 8 have been amended to recite the same step of claim 1, from which they depend, of ascertaining the presence or absence of the marker.

The applicants respectfully submit that claim 1 as currently presented is complete and does not omit an essential step, that being having the patient take the medication. The focus of the subject invention is to ascertain whether a patient has complied in taking a medication as prescribed. To do so, the subject invention teaches providing to a patient a medication with an odorous marker and subsequently sampling and assessing the patient’s breath to determine whether the marker is present therein. Presence of the marker in the patient’s breath is an indicator of patient compliance in taking the medication. That being the case, the step of having the patient take the medication is clearly not an essential step necessary to practice the invention.

The applicants respectfully submit that claim 1 is definite with regard to how the medication is to be taken by the patient and how the breath sample is taken. The fact that claim language may not be precise does not automatically render the claim indefinite under 35 U.S.C. §112, second paragraph. *Seattle Box Co. v. Industrial Crating & Packing Inc.*, 731 F.2d 818, 221 (Fed. Cir. 1984).

Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. The applicants respectfully submit that it is well known to the skilled artisan the various methods for administering a medication to a patient as well as methods involved in sampling exhaled breath. Further, the subject specification at pages 11-14 provides detailed description regarding ways in which a patient can take medication in accordance with the invention; at page 9, detailed description is provided regarding the sampling of exhaled breath. When the claims are read in light of the specification and the knowledge base of those skilled in the art, it is not necessary for the applicants to clarify how medication is to be taken by a patient nor the particular place that a patient's breath sample is obtained. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Claim 5 has been rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps. The applicants respectfully submit that claim 5 does not need to recite the step of how the presence and concentration of the marker are determined by a unique electronic fingerprint produced by sensor technology. However, in an effort to expedite prosecution, the applicants have amended claim 5 to remove the phrase "such that the presence and concentration of the marker is determined." Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants have amended claim 10 to provide further clarification that the marker is provided on the medication in the form of a coating. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 16 and 17 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants have amended claims 16 and 17 clarify that the "results" from the analysis, that being whether or not the marker is present in the breath sample, are recorded and transmitted. Further, the applicants respectfully submit that in light of the subject specification, which describes at p. 15 a method for transmitting analysis results, the skilled artisan would readily

understand what constitutes transmittal of the results as recited in the claims. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 23-25 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants respectfully submit that the claims as presented provide further limitation to the method of claim 1. Specifically, claims 23-25 describe how the marker is made detectable in patient breath. Further, the skilled artisan, having read the specification, would readily recognize the odorous markers that can react with acids in the stomach or enzymes in the mouth to become detectable from those that are absorbed in the gastrointestinal tract and excreted in the lungs. As described above, it is not necessary to include the step of how the patient is to take the medication since the methods of the invention are directed to determining patient compliance in taking a medication. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim 26 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants have amended claim 26 to clarify that the analysis step further includes the step of assessing marker concentration. The applicants respectfully submit that this additional step can be conducted whether the marker is present or absent in the breath sample, as detected by the sensor, since the marker concentration would logically be zero if the marker is absent. In view of the amendment described above, the applicants respectfully submit that claim 26 is now definite and complete and request the reconsideration and withdrawal of its rejection under 35 U.S.C. §112, second paragraph.

Claim 28 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants traverse the grounds for this rejection because claim 28 is definite; however, in an effort to expedite prosecution, the applicants have canceled claim 28, thereby rendering moot its rejection. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim 29 has been rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps. Claim 29 has been amended to clarify the step of combining the odorous marker and medication to produce the final product. The applicant has thus clarified the production method of claim 29 that is useful for assessing patient compliance in taking a medication. In view of

the above amendment, the applicants believe that they have over come the indefiniteness rejection and respectfully request reconsideration and withdrawal of the rejection.

Claims 1, 2, 7-9, 12-21 and 23-30 have been rejected under 35 U.S.C. §102(e) as being anticipated by Katzman (U.S. Patent No. 5,962,335). The subject application is directed to ascertaining patient compliance in taking a medication based on detecting in exhaled breath the presence or absence of an odorous marker associated with the medication. The applicants respectfully traverse the grounds for this rejection because Katzman neither teaches nor suggests the subject invention as currently presented.

Katzman merely describes a method for monitoring patient metabolism of a drug by radiolabeling the drug itself. To monitor patient metabolism, the drug itself is radiolabeled and must undergo patient metabolism before being excreted in exhaled breath. In sharp contrast to Katzman, the instant invention is directed to methods for determining patient compliance in taking medication. The claims of the subject invention are directed to the use of odorous markers and do not require direct labeling of the medication; rather, the subject invention detects an odorous marker that is an additive administered in combination with a medication.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The applicants respectfully submit that Katzman *et al.* does not disclose methods for monitoring patient compliance in taking a medication using odorous compounds. As noted above, the applicants have amended the claims to recite the use of odorous markers in combination with a medication to

assess patient compliance in taking a medication. Because Katzman *et al.* does not disclose the claimed odorous markers, the applicants' claims cannot be said to be anticipated by Katman *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection set forth under 35 U.S.C. §102(e).

Claims 1-3, 6, and 9-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Forester (U.S. Patent No. 4,762,719). The applicants respectfully traverse the grounds for this rejection because Forester does not teach or disclose the claimed invention, that being methods for monitoring patient compliance in taking a medication.

Forester merely teaches a cough drop that includes ingredients that vaporize into the oral and nasal cavities to treat coughing. Forester neither teaches nor suggests sampling exhaled breath from a patient and analyzing the sample to ascertain patient compliance in taking a medication. Further, there is no teaching or suggestion in Forester regarding medications with odorous markers that are detectable in gaseous exhaled breath. Rather, Forester merely teaches a cough product for treating coughs. Because Forester does not disclose every element of the claimed invention, Forester cannot anticipate. Accordingly, reconsideration of this rejection is respectfully requested.

Claims 4 and 5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Forester in view of Payne (WO 98/39470) and in view of Kell (U.S. Patent No. 5,652,146). Applicants respectfully traverse these grounds for rejection and hereby incorporate by reference the comments asserted above regarding Forester.

As noted above, nothing in Forester would have led the skilled artisan to the advantageous methods currently claimed by applicants. Payne merely discloses the diagnosis of a medical condition, such as an infection or disease, using known sensors. Kell discloses the administration of medication and a marker, methadone, which is to be measured in a patient's urine sample to assess patient compliance in taking the medication. The marker disclosed by Kell must be metabolized and excreted in urine and is not detectable in exhaled breath. There is no teaching or suggestion whatsoever by either Forester, Payne, or Kell regarding monitoring patient exhaled breath to assess patient compliance in taking a medication. Specifically, none of the references describe providing to a patient a medication and an odorous marker detectable in gaseous exhaled breath; using a sensor to

detect the presence and or absence of the marker in a sample of exhaled breath taken from the patient; and based on the presence or absence of the marker in the sample, determining whether the patient was compliant in taking the medication.

The Office Action suggests that it would have been obvious to combine the cough medication of Forester with the methods of clinical diagnosis as taught by Payne and Kell's use of markers that must be metabolized to be detectable in urine to provide the subject invention for assessing patient compliance via analysis of exhaled breath. The applicants respectfully disagree.

A *prima facie* finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. The courts have consistently held that when a §103 rejection is based upon a modification of a reference that destroys the intent, purpose, or function of the invention disclosed in the reference, such a proposed modification is not proper and the *prima facie* case of obviousness cannot properly be made. The skilled artisan, having knowledge of Forester, Payne, and Kell would not have any motivation for combining the three technologies to arrive at the claimed invention. Because Forester is directed to a medication to treat coughing, Payne is directed to diagnosing a medical condition, and Kell is directed to providing markers for urine analysis, the skilled artisan would not have considered combining the references to derive a method for ascertaining patient compliance using a medication-marker combination, where the marker is odorous and detectable in gaseous exhaled breath. Further, if the cough medication of Forester were combined with the method of clinical diagnosis of Payne, the intended purpose of Forester's invention, that being to provide a cough drop for treating coughing, would be destroyed if the vapors from the cough drop was used to diagnose a clinical condition (which conceivably was already diagnosed since the cough medication is given to treat the condition of coughing), as suggested in the Office Action.

Here, it is only the applicants' disclosure that provides a teaching for monitoring patient compliance in taking a medication via the detection of odorous markers in exhaled breath, and applicants' disclosure cannot be used to reconstruct the prior art for a rejection under 35 U.S.C §103. This was specifically recognized by the CCPA in *In re Spinnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield the applicants' invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art” *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). As noted above, the skilled artisan would not have found reason to combine Forester, Payne, and Kell to make the claimed invention because the combination of the teachings would destroy the intent, purpose, and function of the invention disclosed in Forester. Thus, the combination of the references as provided in the Office Action that forms the basis of this rejection is not proper and the *prima facie* case of obviousness cannot be made. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 22 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Forester in view of Payne and in view of Ueda. The applicants respectfully traverse, and hereby incorporate by reference the comments asserted above in regard to Forester and Payne.

The shortcomings of Forester and Payne are not cured by Ueda. Ueda discloses a device for sampling and analyzing exhaled breath for components. Although there Ueda suggests using its device for diagnosing a disease (see col. 14, lines 30-35), there is no teaching or suggestion by Ueda regarding analysis of exhaled breath for monitoring patient compliance in taking a medication. As noted above, the skilled artisan would not have found reason to combine Forester and Payne to make the claimed invention because the combination of the teachings would destroy the intent, purpose, and function of the invention disclosed in Forester. Ueda does not cure these shortcomings. Thus,

the applicants respectfully submit that no case of *prima facie* obviousness has been set forth. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection of claims under 35 U.S.C. §103.

Claim 22 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Katzman in view of Payne and in view of Ueda. The applicants respectfully traverse, and hereby incorporate by reference the comments asserted above in regard to Katzman, Payne, and Ueda. Katzman describes methods for monitoring patient metabolism using radiolabeled medications; Payne describes methods for clinical diagnosis; and Ueda describes a device for analyzing exhaled breath components. None of the references describe or suggest methods for monitoring patient compliance in taking a medication. In fact, none of the references describe or even suggest providing to a patient a medication in combination with an odorous marker detectable in gaseous exhaled breath. Because the deficiencies of Katzman are not cured by either Payne or Ueda relied on in the office action, this obviousness rejection should be withdrawn. Reconsideration is respectfully requested.

In view of the foregoing remarks and the amendments above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Margaret Efron
Patent Attorney
Registration No. 47,545
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

MHE/la